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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/505,250

05/13/2005

Derek O'Hagan

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04/03/2008

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY R338

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

04/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/505,250

Applicant(s)

O'HAGAN ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 14-19, 21-32 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 20, 33 and 35-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 2/28/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-47 are pending in the application.
2. In the prior action, mailed on October 10, 2007, claims 1-35 were pending; with claims 1-13, 20, and 35 rejected; claim 33 objected to; and claims 14-19, 21-32, and 34 withdrawn from consideration.
3. In the Response of January 10, 2008, the Applicant amended claims 1 and 33; and added new claims 36-47.
4. Claims 1-13, 20, 33, and 35-47 are under consideration.
5. In view of the new rejections over claim 33, the action is made Non-Final.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on February 28, 2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **(New Rejection)** Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "high-shear" in claim 46 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not

provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim is therefore rejected as indefinite.

Claim Rejections - 35 USC § 102

9. **(Prior Rejections- Withdrawn)** Claims 1-5, 7, and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Soriano et al. (reference C12 in the July 2005 IDS). Claims 1-7, 10-12, and 35 were rejected under 35 U.S.C. 102(b) as being anticipated by O'Hagan et al (WO 94/27718). In view of the amendment of the claims, and the argument pursuant thereto, the rejections are withdrawn.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **(New Rejection)** Claims 1-7, 10-12, 35-38, 41, 42, and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hagan as previously applied to claims 1-7, 10-12, and 35, and further in view of O'Hagan et al. (O'Hagan II- WO 98/33487). The Applicant traversed the prior rejection over O'Hagan by amending the claims to require that the microparticles do not encapsulate the polypeptide antigen (or are formed in the absence of the antigen). Such was not taught or suggested by O'Hagan. However, O'Hagan II teaches the

Art Unit: 1648

adsorption of antigens to microparticles instead of the encapsulation of the antigens so as to improve ability of the antigen to induce a CTL response. Pages 3-4. It would therefore have been obvious for those of ordinary skill in the art to modify the particles suggested by O'Hagan as suggested by the teachings of O'Hagan II to improve the ability of the resulting compositions to induce anti-viral immune responses. In addition, O'Hagan II teaches the use of an emulsion technique such as is described by claims 33 and 44-46 to make the particles. See e.g., page 30 (Example 7). The teachings of the cited references therefore render the claimed inventions obvious.

12. **(Prior Rejection- Restated and Maintained)** Claim 13 was rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hagan as applied to claims 1-7, 10-12, and 35 above, and further in view of Krieg et al. (U.S. 6,207,646). The rejection is restated as a rejection of claims 13 and 43 over the teachings of O'Hagan and O'Hagan II as applied above, further in view of Krieg. The Applicant traverses the rejection for the reasons asserted with respect to the anticipation rejection over O'Hagan. The argument is not found persuasive in view of the restatement of the rejection.

13. **(Prior Rejection- Restated and Maintained)** Claims 8 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hagan as applied to claims 1-7, 10-12, and 35 above, and further in view of Pizza et al., (Science 287:1816-20) and in light of WO 2004/032958. The rejection is restated as a rejection of claims 8, 9, 39, and 40 over the teachings of O'Hagan in view of O'Hagan II as applied above, and further in view of Pizza and in light of

WO 2004/032958. The Applicant traverses the rejection for the reasons asserted with respect to the anticipation rejection over O'Hagan. The argument is not found persuasive in view of the restatement of the rejection.

14. **(Prior Rejection- Restated and Maintained)** Claim 20 was rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hagan as applied to claims 1-7, 10-12, and 35 above, and further in view of Constantino et al. (Vaccine 17:1251-63). The rejection is restated as a rejection of claim 20 over the teachings of O'Hagan in view of O'Hagan II as applied above, and further in view of Constantino. The Applicant traverses the rejection for the reasons asserted with respect to the anticipation rejection over O'Hagan. The argument is not found persuasive in view of the restatement of the rejection.

15. **(New Rejection- based on reference cited in IDS)** Claims 1, 7, 10, 20, 33, 35, 38, 44 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olivier et al. (reference 1 of the February 2008 IDS) in view of the teachings of Jeon et al. (Int J Pharmaceutics 207:99-108- of record in the July 2005 IDS). These claims read on microparticles comprising a polymer such a polycyanoacrylate and having a polypeptide containing molecule adsorbed thereto, wherein the particle is made without surfactant, but wherein the polypeptide is not present during the formation of the particle and is therefore not encapsulated or entrapped by the particle.

Olivier teaches the making of microparticles comprising such a polymer and having a glycoprotein adsorbed onto the particles surface. Abstract. However, the reference teaches the use of a surfactant (dextran) in the making of the particles. Page 350 (section 2.2). Jeon teaches

that it is desirable not to use a surfactant. Page 100, right column. It would therefore have been obvious to those of ordinary skill in the art to have made the particles of Olivier without surfactant to determine the effect of such a method of making on the ability of the particles to adsorb glycol- or other proteins on its surface. The combined teachings of the cited references therefore render the claimed invention obvious.

16. **(New Rejection- based on reference cited in IDS)** Claims 1-7, 10, 20, 33, 35-38, and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olivier and Jeon as applied to claims 1, 7, 10, 20, 33, 35, 38, 44 and 47 above, and further in view of O'Hagan (WO 94/27718- previously of record). Claims 1, 7, 10, 20, 33, 35, 38, 44 and 47 have been described above. The additional claims describe embodiments wherein the particles are made of a poly- α -hydroxy acid such as PLGA. The teachings of Olivier and Jeon have been described above. Olivier teaches the benefit of making a particle comprising a glycoprotein adsorbed thereto. Jeon teaches the benefit of making a microparticle without the use of a surfactant. Further, each of Jeon and O'Hagan teach the use of PLGA for the making of microparticles. It would have been obvious to those of ordinary skill in the art to have used PLGA in the place of the functionally equivalent polymer used by Olivier for the production of the particles suggested by Olivier and Jeon. Thus, the combined teachings of the cited art render the claimed invention obvious.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(c), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

18. Applicant is advised that should claim 1 be found allowable, claim 47 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The only difference between the two claims is that in claim 1, the composition is described as being formed in the absence of a polypeptide-containing molecule (a product by process limitation) whereas in claim 47 the composition is described as not entrapping or encapsulating polypeptide-containing molecules (a structural limitation). However, the resulting claimed microparticle in each claim is identical.

Conclusion

19. No claims are allowed.
20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yang et al., J Microencapsulation 18:223-36 (of record in the July 2005 IDS). This reference indicates that it was known in the art that emulsion based methods for microparticle production may be performed surfactant-free.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648